DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 16 2009

Re: XIENCE V EECSS
Docket No.: FDA-2008-E-0551

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,451,233, filed by Abbott Cardiovascular Systems Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for XIENCE V EECSS, the medical device claimed by the patent.

The total length of the regulatory review period for XIENCE V EECSS is 1,157 days. Of this time, 759 days occurred during the testing phase and 398 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: May 4, 2005.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on May 4, 2005.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: June 1, 2007.

   The applicant claims the premarket approval application (PMA) XIENCE V EECSS (PMA 70015) was submitted in three modules and that Module 1 was initially submitted on July 14, 2006. The applicant claims July 14, 2006, as the date PMA 70015 was initially submitted. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records indicates that PMA 70015 was submitted as a complete application on June 1, 2007, which is considered to be the initially submitted date for PMA 70015.

3. The date the application was approved: July 2, 2008.

   FDA has verified the applicant's claim that PMA 70015 was approved on July 2, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Daniel J. Hulseberg
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